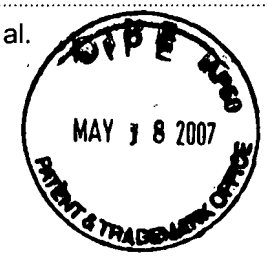
PATENT Case No. ITR0053YP

IAW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Pallaoro et al.



Serial No. 10/582,621

Filed: June 12, 2006

For: METHOD FOR IDENTIFYING HISTONE DEACETYLASE INHIBITORS

Art Unit: --

Examiner: --

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By _____ Date 5/15/07

PATENT Case No. ITR0053YP

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION	
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

☐ the attached information is filed within three months of the filing date of the captioned case.

☑ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.

☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).

☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

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☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: JOHN DAVID REILLY
Attorney For Applicant(s)
Reg. No. 43,039
MERCK & CO., INC.
Patent Dept., RY60-30
P.O. Box 2000
Rahway, N.J. 07065-0907
(732)594-6914

Date: May 15, 2007

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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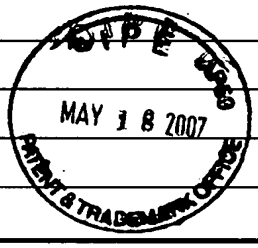
Sheet	1	of	4

COMPLETE IF KNOWN	
Application Number	10/582,621
Filing Date	June 12, 2006
First Named Inventor	Pallaoro et al.
Group Art Unit	--
Examiner Name	--
Attorney Docket Number	ITR0053YP



U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		5741657		Tsien et al.	04/21/1998
		5807692		Kinzler et al.	09/15/1998
		5871968		Kinzler et al.	02/16/1999
		5955604		Tsien et al.	09/21/1999
		5993845		Geerts et al.	11/30/1999
		6068987		Dulski et al.	05/30/2000
		6291162		Tsien et al.	09/18/2001
		6387673		Evans et al.	05/14/2002
		6472205		Tsien et al.	10/29/2002
		6511990		Breslow et al.	01/28/2003
		6541661		Delorme et al.	04/01/2003
		6544957		Kern et al.	04/08/2003
		6638530		Ishibashi et al.	10/28/2003

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
			WO 96/30540		The Regents of the Univ. of California	10/03/1996
			WO 95/20280		France Telecom and Telediffusion de France	07/27/1995
			WO 03/020930		The Board of Trustees of the Univ. of Illinois and University of Dundee	03/13/2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

COMPLETE IF KNOWN	
Application Number	10/582,621
Filing Date	June 12, 2006
First Named Inventor	Pallaoro et al.
Group Art Unit	--
Examiner Name	--
Attorney Docket Number	ITR0053YP

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Goodwin et al., Molecular Pharmacology, Vol. 56 (1999), pp. 1329-1339, "The orphan human pregnane X receptor mediates the transcriptional activitation of CYP3A4 ..."
	AB	Xing et al., J. Receptor & Signal Transduction Research, Vol. 20 (2000), pp. 189-210, "A fluorescent reporter assay for the detection of ligands acting through G1 protein-coupled receptors"
	AC	Kramer et al., Trends in Enocrinol & Metab., Vol. 12 (2001), pp. 294-300, "Histone deacetylase as a therapeutic target"
	AD	Colletti et al., Bioorg. & Med. Chem. Letters, Vol. 11 (2001), pp. 113-117, "Broad spectrum antiprotozoal agents that inhibit histone deacetylase: ..."
	AE	Archer et al., Curr. Opin. in Genetics & Develop., Vol. 9 (1999), p. 171-174, "Histone acetylation and cancer"
	AF	Colletti et al., Bioorg. & Med. Chem. Letters, Vol.11 (2001), pp. 107-111, "Broad spectrum antiprotozoal agents that inhibit histone deacetylase: ..."
	AG	Sowa et al., Biochem. & Biophys. Res. Comm., Vol. 241 (1997), pp. 142-150, "Histone eacetylase inhibitor activates the WAF1/Cip1 gene ..."
	AH	Galarneau et al., Nature Biotech., Vol. 20 (2002), pp. 619-622, "Beta-lactamase potein fragment complementation assays in vivo and in vitro ..."
	AI	Egawa et al., Biol. Pharm. Bull., Vol. 21 (1998), pp. 899-904, "Identification of active substances from Streptomyces culture ..."
	AJ	Hustert et al., Drug Metab. & Disposition, Vol. 29 (2001), pp. 1454-1459, "Natural protein variants of pregnane X receptor with altered transactivation ..."
	AK	Zlokarnik et al., Science, Vol. 279 (1998), p. 84-88, "Quantitation of transcription and clonal selection of single living cells ..."
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	AM	Nare et al., Anal. Biochem., Vol. 267 (1999), pp. 390-396, "Development of a scintillation proximity asasay for histone deacetylase using a biotinylated peptide ..."
	AN	Huang et al., Oncogene, Vol. 19 (2000), pp. 5712-5719, "Activation of the p21 WAF1/CIP1 promoter independent of p53 by the histone deacetylase inhibitor ..."
	AO	Grozinger et al., Chem. & Biol., Vol. 9 (2002), pp. 3-16, "Deacetylase Enzymes: Biological functions and the use of small-molecule inhibitors"

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COMPLETE IF KNOWN	
Application Number	10/582,621
Filing Date	June 12, 2006
First Named Inventor	Pallaoro et al.
Group Art Unit	--
Examiner Name	--
Attorney Docket Number	ITR0053YP

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AP	Goodwin et al., Molec. Pharmacol., Vol. 62 (2002), pp. 359-365, "Transcriptional regulation of the human CYP3A4 gene by the constitutive ..."
	AQ	Marks et al., Nature Rev., Vol. 1 (2001), pp. 194-202, "Histone deacetylases and cancer: causes and therapies"
	AR	Meinke et al., Curr. Med. Chem., Vol. 8 (2001), pp. 211-235, "Histone deacetylase: A target for antiproliferative and antiprotozoal agents"
	AS	Raucy et al., J, Pharmacol. & Exper. Therapeutics, Vol. 303 (2002), pp. 412-423, "A cell-based reporter gene assay for determining induction of CYP3A4 ..."
	AT	Meinke et al., J. Med. Chem., Vol. 43 (2000), pp. 4919-4922, "Synthesis of apicidin-derived quinolone derivatives: parasite-selective histone deacetylase ..."
	AU	Sambucetti et al., J. Biol. Chem., Vol. 274 (1999), pp. 34940-34947, "Histone deacetylase inhibition selectively alters the activity and expression of cell cycle ..."
	AV	Cress et al., J. Cell. Physiol., Vol. 184 (2000), pp. 1-16, "Histone deacetylases, transcriptional control, and cancer"
	AW	Nakano et al., J. Biol. Chem., Vol. 272 (1997), pp. 22199-22206, "Butyrate activates the WAF1/Cip1 gene promoter through Sp1 sites ..."
	AX	Han et al., J. Biol. Chem., Vol. 276 (2001), pp. 42084-42090, "Activation of p21 WAF1/Cip1 transcription through Sp1 sites ..."
	AY	Drocourt et al., J. Biol. Chem., Vol. 277 (2002), pp. 25125-25132, "Expression of CYP3A4, CYP2B6, and CYP2C9 is regulated by the vitamin D ..."
	AZ	Sowa et al., Cancer Res., Vol. 59 (1999), pp. 4266-4270, "Sp3, but not Sp1, mediates the transcriptional activation of the p21/WAF1/Cip1 gene ..."
	BA	Ju et al., Cancer Res., Vol. 63 (2003), pp. 2891-2897, "Histone deacetylase inhibitors activate p21 WAF1 expression via ATM"
	BB	Furumai et al., Cancer Res., Vol. 62 (2002), pp. 4916-4921, "FK228 (depsipeptide) as a natural prodrug that inhibits Class I ..."
	BC	Zlokarnik et al., Science, Vol. 279 (1998), pp. 84-88, "Quantitation of transcription and clonal selection of single living cells ..."
	BD	Taunton et al., Science, Vol. 272 (1996), pp. 408-411, "A mammalian histone deacetylase related to the yeast transcriptional regulator Rpd3p"

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Sheet	4	of	4

COMPLETE IF KNOWN	
Application Number	10/582,621
Filing Date	June 12, 2006
First Named Inventor	Pallaoro et al.
Group Art Unit	--
Examiner Name	--
Attorney Docket Number	ITR0053YP

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	BE	Richon et al., PNAS, Vol. 97 (2000), pp. 10014-10019, "Histone deacetylase inhibitor selectively induces p21WAF1 expression and gene-associated histone acetylation"
	BF	Meinke et al., Tetra. Letters, Vol. 41 (2000), pp. 7831-7835, "Synthesis of side chain modified apicidin derivatives: potent mechanism-based histone ..."
	BG	Colletti et al., Tetra. Letters, Vol. 41 (2000), pp. 7837-7841, "Design and synthesis of histone deacetylase inhibitors: the development of apicidin ..."
	BH	Colletti et al., Tetra. Letters, Vol. 41 (2000), pp. 7825-7829, "Tryptophan-replacement and indole-modified apicidins: synthesis of potent and selective ..."
	BI	Archer et al., PNAS, Vol. 95 (1998), pp. 6791-6796, "p21WAF1 is required for butyrate-mediated growth inhibition of human colon cancer cells"
	BJ	Xiao et al., J. Cell. Biochem., Vol. 73 (1999), pp. 291-302, "Both Sp1 and Sp3 are responsible for p21waf1 promoter activity induced by histone ..."
	BK	Genbank No. U24170, "Human p21 (WAF1) gene, partial promoter sequence", submitted April 5, 1995
	BL	Genbank No. AF497972, "Homo sapiens cyclin-dependent kinase inhibitor 1A (p21, Cip1) (CDKN1A) gene, complete cds", submitted April 2, 2002
	BM	Genbank No. Z85996, "Human DNA sequence from clone RP3-431A14 on chromosome 6p21, complete sequence, submitted January 16, 2007
	BN	Perez et al., Proc. of the Am. Assoc. for Cancer Res., 93rd Annual Meeting, March 2002, Vol. 13, Abstract No. 3671, "Discovery and SAR of NVP-LAQ824, a novel histone deacetylase inhibitor with in vitro and in vivo antitumor activity"

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